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**UNITED STATES DEPARTMENT OF COMMERCE****United States Patent and Trademark Office**Address: COMMISSIONER OF PATENTS AND TRADEMARKS  
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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
09/011,797	07/23/98	PARMENTIER	M VANIMA72.001A <i>BT</i>

HM12/0529

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EXAMINER

MURPHY, J.

ART UNIT	PAPER NUMBER
1646	<i>14</i>

DATE MAILED: 05/29/01

Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks

<b>Office Action Summary</b>	Applicant No.	Applicant(s)
	09/011,797	PARMENTIER ET AL.
	Examiner	Art Unit
	Joseph F Murphy	1646

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

#### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

#### Status

1) Responsive to communication(s) filed on 23 March 2001.

2a) This action is FINAL.                    2b) This action is non-final.

3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

#### Disposition of Claims

4) Claim(s) 35-42, 47-52, 57 and 58 is/are pending in the application.

4a) Of the above claim(s) 48-52, 57-58 is/are withdrawn from consideration.

5) Claim(s) \_\_\_\_\_ is/are allowed.

6) Claim(s) 35-42 and 47 is/are rejected.

7) Claim(s) \_\_\_\_\_ is/are objected to.

8) Claims \_\_\_\_\_ are subject to restriction and/or election requirement.

#### Application Papers

9) The specification is objected to by the Examiner.

10) The drawing(s) filed on \_\_\_\_\_ is/are objected to by the Examiner.

11) The proposed drawing correction filed on \_\_\_\_\_ is: a) approved b) disapproved.

12) The oath or declaration is objected to by the Examiner.

#### Priority under 35 U.S.C. § 119

13) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a) All b) Some \* c) None of:

1. Certified copies of the priority documents have been received.
2. Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

14) Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

#### Attachment(s)

15) Notice of References Cited (PTO-892)

16) Notice of Draftsperson's Patent Drawing Review (PTO-948)

17) Information Disclosure Statement(s) (PTO-1449) Paper No(s) \_\_\_\_\_.

18) Interview Summary (PTO-413) Paper No(s) \_\_\_\_\_.

19) Notice of Informal Patent Application (PTO-152)

20) Other: \_\_\_\_\_

## **DETAILED ACTION**

### ***Formal Matters***

Claims 35 and 38 were amended in Paper No. 13, 3/30/2001. Claims 35-42, 47-52 and 57-58 are pending. Claims 48-52 and 57-58 stand withdrawn from consideration pursuant to 37 CFR 1.142(b). Claims 35-42 and 47 are under consideration.

The text of those sections of Title 35, U. S. Code not included in this action can be found in a prior Office Action.

### ***Response to Amendment***

The rejection of claims 35-42 and 47 under 35 USC § 112, second paragraph has been withdrawn based on Applicant's arguments.

### ***Claim Rejections - 35 USC § 112 first paragraph***

Claims 35-36, 38 and 47 stand rejected under 35 USC § 112, first paragraph, for reasons of record set forth in Paper No. 8, 3/29/2000, and maintained in Paper No. 11, 11/20/2000, because the specification, while being enabling for a substantially purified polypeptide comprising an amino acid selected from the group consisting of SEQ ID NOs: 2, 3 and 4, does not reasonably provide enablement for an isolated peptide encoded by a polynucleotide which corresponds to at least 70% or 90% of the SEQ ID NO: 1 or its complementary strand.

Applicant argues that examples are provided in the specification of peptides which bear greater than 70 % homology to an amino acid sequence as set forth in SEQ ID NO: 1 and bind ORL1, that one of skill in the art would know how to use these sequences to identify additional peptides with the requisite homology and function, and that such peptides exist in the art.

However, in *Amgen Inc. v. Chugai Pharmaceutical Co. Ltd.*, 18 USPQ2d 1016 (Fed. Cir. 1991), the court ruled that a claim to a large genus of possible genetic sequences encoding a protein with a particular function that needs to be determined subsequent to the construction of the genetic sequences may not find sufficient support under 35 USC 112, 1st paragraph, if only a few of the sequences that meet the functional limitations of the claim are disclosed and if undue experimentation would be required of one skilled in the art for determining other genetic sequences embraced by the claim. In the instant case there are a large number of nucleic acid sequences which are 'at least 70% identical to SEQ ID NO: 1 or its complement' however these sequences encode various unrelated proteins. Therefore, while the specification provides the necessary guidance to make the polynucleotide set forth in SEQ ID NO: 1 and the polypeptides set forth in SEQ ID NO: 2, 3, and 4 it does not provide the necessary guidance for one of skill in the art to use the nucleic acid sequences which do not encode a ligand of ORL1 receptor protein.

Furthermore, as evidenced by the Mikayama and Voet references, the protein art is unpredictable with regards to the effects of mutations on the function of polypeptides. As set forth in *In re Fisher*, 166 USPQ 18 (CCPA 1970), compliance with 35 USC 112, first paragraph requires:

that scope of claims must bear a reasonable correlation to scope of enablement provided by specification to persons of ordinary skill in the art; in cases involving predictable factors, such as mechanical or electrical elements, a single embodiment provides broad enablement in the sense that, once imagined, other embodiments can be made without difficulty and their performance characteristics predicted by resort to known scientific laws; in cases involving unpredictable factors, such as most chemical reactions and physiological activity, scope of enablement varies inversely with degree of unpredictability of factors involved.

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Based on the unpredictability of the protein art as evidenced by the Mikayama and Voet references, these claims stand rejected under 35 USC § 112, first paragraph.

***Conclusion***

No claim is allowed.

**THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

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***Advisory Information***

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Joseph F. Murphy whose telephone number is 703-305-7245. The examiner can normally be reached on M-F 7:30-5:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Yvonne Eyler can be reached on 703-308-6564. The fax phone numbers for the organization where this application or proceeding is assigned are 703-305-3014 for regular communications and 703-308-0294 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-0196.

Joseph F. Murphy, Ph. D.  
Patent Examiner  
Art Unit 1646  
May 23, 2001

*Prema Mertz*  
PREMA MERTZ  
PRIMARY EXAMINER